REMARKS

In this Amendment, Claims 1 and 11 are amended and claims 2-4 and 12-14 are canceled without prejudice. Claim 20 was previously canceled. Claim 21 was previously added. Claims 1, 5-11, 15-19 and 21 remain before the Examiner for reconsideration.

In the Office Action dated April 8, 2004, the Examiner rejected Claims 1 and 11 under 35 U.S.C. 102(b) as being anticipated by Lajus. Specifically the Examiner asserted that:

> The Lajus Patent shows in figure 5, a plunger for use in a syringe comprising a body portion having an inner wall, a discharge end and a transition region defined between the body portion and the discharge end, the plunger comprising a base, a plunger surface comprising a seal; wherein increases in pressure caused by movement of the plunger in a syringe compresses the seal portion between the inner wall of the syringe and the side portion of the base to create a dynamic seal between the seal portion and the inner wall.

Applicants respectfully traverse the Examiner's rejection.

To assert anticipation under Section 102(b) the cases hold that the Examiner:

> must show that each element of the claim in issue is found, either expressly described or under principles on inherency, in a single prior art reference, or, that the claimed invention was previously known or embodied in a single prior art device or practice.

Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. Denied, 465 U.S. 1026 (1984); Tyler Refrigeration v. Kysor Industrial Corp., 777 F.2d 687, 689, 227 USPQ 845, 846-47 (Fed. Cir. 1984) (judgment of anticipation reversed). "In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in the light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference." Lindemann, 730 F.2d at 1458, 221 USPQ at 485; Kalman, 713 F.2d at 771, 218 USPQ at 789.

"The test for determining if a reference anticipates a claim of a patent is whether the reference contains within its four corners adequate directions for the practice of the patent claim ... ." Kistler Instrument A.G. v. United States, 628 F.2d 1303, 1311, 203 USPQ 511, 519, aff'd., 211 USPQ 920 (Ct. Cl. 1980). The reference, whether foreign or domestic, patent or otherwise, must be construed strictly for what it "clearly and definitely discloses." Application of Boling, 292 F.2d 306, 310-11, 130 USPQ 161, 164 (CCPA 1961); Aluminum Co. of Am. v. Sperry Products, Inc., 285 F.2d 911, 922, 127 USPQ 394, 403 (6th Cir. 1960), cert. denied, 368 U.S. 890 (1961). A patent is not anticipated by a reference "unless the latter exhibits the invention in such full, clear and exact terms as to enable any person skilled in the art to practice it without making experiments." 285 F.2d at 922, 127 USPQ at 403.

Initially, it is not clear to what "seal" the Examiner is referring when the Examiner asserts that Lajus, in Figure 5, discloses "a plunger surface comprising a seal; wherein increases in pressure caused by movement of the plunger in a syringe compresses the seal portion between the inner wall of the syringe and the side portion of the base to create a dynamic seal between the seal portion and the inner wall." Applicants believe that the Examiner is possibly referring to end reinforcement 60 of Lajus. In that regard, Lajus discloses at Col. 5, lines 38-42:

> When the tip 90 is completely pushed into the hollow piston 50, the end reinforcement 60 is strongly pressed against the internal wall of the syringe body 1 and insures excellent sealing between the piston 50 and the body 1.

Lajus thus discloses that reinforcement 60, which extends from piston 50, is pressed against the internal wall of the syringe. Unlike the present invention, however, Lajus does not disclose or suggest that increasing pressure within the syringe corresponding to movement of a plunger therethrough compresses a seal portion of a plunger surface between the inner wall of the syringe and the side portion of a plunger base to create a dynamic seal between the seal portion and the inner wall of tile syringe. Moreover, contrary to the present invention, Lajus does not disclose or suggest a syringe plunger comprising: (i) a base comprising a side portion that is tapered so that the

diameter of the side portion of the base decreases from a rearward axial position to a forward axial position thereof and (ii) a plunger surface disposed on at least a portion of the base and comprising a seal portion comprising an exterior surface in contact with the inner wall of the syringe and an inner wall that is tapered so that the diameter of the inner wall decreases from a rearward axial position to a forward axial position thereof. In the present invention, an increase in pressure caused by movement of the plunger in the syringe compresses the seal portion between the inner wall of the syringe and the side portion of the base to create a dynamic wedge seal between the seal portion and the inner wall of the syringe. The dynamic seal of the present invention creates a seal between the plunger surface and the inner wall of the syringe even in the case that the inner wall of the syringe expands, as occurs, for example, in high pressure injection procedures. In that regard, the advantages of the dynamic wedge seal of the present invention are set forth on page 24 of the specification as follows:

> As the internal pressure of the syringe system increases, the elastomeric material in the region of 350 of seal cover 310 tends to slide along surface 340 of base 312 parallel to axis A of plunger 15. The sliding action of these components in response to increased internal syringe pressure forces seal cover 310 to exert a radial force on the inside wall of syringe barrel 50', thereby creating a dynamic 'wedge' seal system.
>
> In the case of 'static' seal systems (for example 0-rings), used on current syringe systems, as the internal syringe pressure increases, the radial expansion of the vessel must be minimal to ensure an adequate seal. Such static sealing systems are thus generally acceptable in a syringe barrel system where radial barrel growth is negligible. In a prefillable syringe system, however, radial growth in response to increases in internal pressure can be substantial due to the weakness of certain syringe materials, and the lack of a pressure jacket. For example, radial growth of the barrel 50 is typically observed under internal pressures achieved during a powered injection. The wedge dynamic seal provides a dynamic seal within such a relatively flexible, radially expanding syringe barrel under relatively high internal pressures.

Under the appropriate analysis as set forth above, Lajus does not and cannot anticipate the present invention.

In the interest of expedient prosecution of several embodiments of the present invention, Applicants have amended the claims to more clearly set forth those embodiments. Applicants reserve the right to reassert the claims as previously presented.

The Examiner also rejected Claims 2-10, 12-19, and 21 under 35 U.S.C. 103(a) "as being unpatentable over Lajus in view of Farkas, Nussbaumer et al., Neer et al, and Linder. Specifically the Examiner asserted that:

> Lajus does not expressly disclose specific tapering angles used in the plunger design, and conical and hemispherical shapes. However, these enhancements are conventional as evidenced by the teachings of Farkas, Nussbaumer et al., Neer et al, and Linder.
>
> The listed patents show variations in the tapering angle that are within the disclosed ranges. Additionally, Nussbaumer et al. discloses a conical plunger. Accordingly, based on the conventionality of the disclosed enhancements, for a person of ordinary skill in the art, their use in plunger designs would be considered obvious design alternatives.

For the reasons set forth above, Applicants respectfully traverse the Examiner's rejection. Neither Farkas, Nussbaumer et al., Neer et al, Linder, nor any combination thereof overcome the deficiencies of Lajus set forth above. In that regard, neither Farkas, Nussbaumer et al., Neer et al, Linder, nor any combination thereof disclose or suggest that increasing pressure within a syringe corresponding to movement of a plunger therethrough compresses a seal portion of a plunger surface between the inner wall of the syringe and a side portion of a plunger base to create a dynamic seal between the seal portion and the inner wall of tile syringe. Moreover, neither Farkas, Nussbaumer et al., Neer et al, Linder, nor any combination thereof disclose or suggest a syringe plunger comprising: (i) a base comprising a side portion that is tapered so that the diameter of the side portion of the base decreases from a rearward axial position to a forward axial position thereof and (ii) a plunger surface disposed on at least a portion of the base and comprising a seal portion comprising an exterior surface in contact with the inner wall of the syringe and an inner wall that is tapered so that the diameter of the inner wall decreases from a rearward axial position to a forward axial position thereof.

In view of the above amendments and remarks, the applicants respectfully requests that the Examiner withdraw the rejections of the claims, indicate the allowability of the claims- and arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,

MARK W. HITCHINS et. al.

By _____

Henry E. Bartony, Jr.
Reg. No. 34,772

MEDRAD, INC.
One Medrad Drive
Indianola, PA 15051
(412) 767-2400 (phone)
(412) 767-8899 (fax)
Attorney for Applicants